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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,329	11/18/2003	Fred H. Burbank	R0368-04000	5236

7590 03/19/2007  
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EXAMINER
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TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,329	<b>Applicant(s)</b> BURBANK ET AL.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 10-13, 40-43, 45, 46 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-13, 40-43, 45, 46 and 50-53 is/are rejected.
- 7) ☒ Claim(s) 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to applicant's amendment received on 24 January 2007. All corrections made have been accepted.

#### ***Claim Objections***

1. Claim 45 is objected to because of the following informalities: it depends on a claim that has been cancelled. Replace "44" with --40--. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 42, 43 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohajer (Patent No. 5,464,409). Mohajer discloses an intravaginal device (see Figure 7) comprising an elongated resilient (column 4, line 1), or "malleable", guide rail (30) with an end (32) "configured to" receive and guide a medical instrument (whether or not it is attached to a slidable coupling element since the distal end is "free" or open), and a tissue grasping mechanism (tenaculum 56) secured to the distal portion of the guide rail (30) having two elongated members (not labeled) pivotally connected at a pivot point (not labeled) on the same side of the guide rail (30) having finger grips (not labeled) and a sharp point (the elongated member tapers from a large diameter to a

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narrow point). Mohajer further discloses a "collar" (shield member 12) mounted on the guide rail (30) that moves in a longitudinal direction (column 2, lines 57-60).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 10-13 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohajer. Mohajer discloses a device as described above, as well as other embodiments. Figure 1 shows a uterine manipulator (10) comprising a guide rail (18), wherein the distal tip is split into bifurcated portions (14 and 16; see Figure 5) having different radii of curvature. Figure 5 further shows an embodiment wherein the distal tip is expandable (44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device as taught by Mohajer in order to provide a device that can hold itself in place during the procedure by engaging

portions of the uterus, uterine cavity, and cervix (column 4, lines 48-53 and column 5, lines 45-49), thus facilitating the procedure.

6. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohajer in view of Hasson (Patent No. 5,037,430). Mohajer discloses a device as described above, however, does not disclose a securing element on the tissue-grasping element. Hasson discloses a clamp for gynecological instruments (Figure 2). Hasson teaches a securing element (ratcheted lock tabs 38) on the tissue-grasping element (10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the tissue grasping element of Mohajer with a securing element as taught by Hasson in order to hold the tissue grasping element in the clamped position (column 3, lines 13-15).

7. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohajer in view of Hasson (Patent No. 5,562,680). Mohajer discloses a device as described above, however, does not disclose the collar is threaded. Hasson discloses an apparatus (Figure 6) having an elongated guide rail (34; since it is the central portion of the device) with a "collar" (extension 36) that supports the uterus in a desired working orientation (column 4, lines 52-54). Hasson teaches a threaded connection between the collar (36) and guide rail (column 4, lines 54-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a threaded connection between the collar and guide rail of Mohajer as taught by Hasson in order to be able to keep the collar from sliding when in a selected position, while still enabling a way to provide a custom fitting (column 4, lines 55-63).

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the threads on an exterior portion of the guide rail (rather than an interior portion) and on the interior of the collar (rather than on the exterior), since the "collar" of Mohajer is disposed over the guide rail, not through it.

### ***Response to Arguments***

8. Applicant's arguments filed 24 January 2007 have been fully considered but they are not persuasive. Applicant argues primarily that Mohajer fails to teach or suggest every feature of the claimed invention. Applicant states that the device of Mohajer does not appear to be able to direct a medical device on the rail to a desired location and that Mohajer fails to teach or suggest a second elongated member with a tissue engaging distal tip configured to grasp uterine tissue at a location proximal to the distal end of the guide rail. Examiner respectfully disagrees. The functional language has been carefully considered, but deemed not to impose any structural limitations on the claims to make them patentably distinguishable over Mohajer's device. Mohajer discloses a *slidable collar* (see rejection above), which is capable of being used as claimed if one desires to do so. Furthermore, Figure 7 clearly shows a second elongated member with a tissue engaging distal tip capable of grasping uterine tissue at a location proximal to the distal end of the guide rail (tenaculum; see rejection above for details).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson  
March 9, 2007



**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

3/17/07